K012638

NOV 0 8 2001

ALLIANCE
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510(k) Summary of Safety and Effectiveness

Submitter:

Alliance Medical Corporation
10232 South 51st Street
Phoenix, Arizona 85044

Contact:

Don Selvey
Vice President, Regulatory Affairs and Quality Assurance
(480) 763-5300

Date of preparation:

August 10, 2001

Name of device:

Trade name: Alliance Medical Corporation
Reprocessed Laparoscopic/Endoscopic Instruments

Common name: Laparoscopic/Endoscopic Instruments
Classification name: Endoscope and Accessories
Gynecologic Laparoscope and Accessories

Predicate devices:

Reprocessed devices:

Manufacturer	Description	Model
Ethicon	Endopath ® Babcock Grasper	BB10
Ethicon	Endopath ® Right Angle Dissector	BRK10
Ethicon	Endopath ® Allis Clamp	BA10
Ethicon	Endopath ® Bowel Clamp	BC10
Ethicon	Endopath ® Kelly Clamp	BK10
Ethicon	Endopath ® Lung Clamp	ENDLC
Ethicon	Endopath ® Atraumatic Babcock Grasper	AB10
Ethicon	Endopath ® Right Angle Dissector	TRK 10
Ethicon	Endopath ® Modified Allis Clamp	MBA 10
Ethicon	Endopath ® Babcock Grasper	BB5

K#	Device Description	Product code
K933160	Ethicon Endo-surgery Procedure Kits	GCJ
K930933	Ethicon Endopath ® Endoscopic Surgical Instruments	GCJ

Device description:	Laparoscopic/endoscopic instruments consist of a rigid plastic handpiece with loop handles connected to the distal end effector jaw by an elongated, narrow-diameter insulated shaft. The devices are designed to be inserted through an appropriately sized trocar sleeve or cannula. The jaws are operated by the handpiece loop handles and may be shaped as scissors, dissectors, or graspers. The jaws of some models may be rotated by manipulating controls on the handpiece. Grasper models may feature ratchet jaws to lock and hold tissue, again operated at the handpiece.
Intended use:	Reprocessed laparoscopic/endoscopic instruments, including scissors, dissectors, and graspers, are intended for use in minimally invasive procedures.
Indications statement:	Reprocessed laparoscopic/endoscopic instruments, including scissors, dissectors, and graspers, are to be used for patients requiring minimally invasive surgical procedures to manipulate and manage internal soft tissue by grasping, cutting or dissecting tissue.
Technological characteristics:	The intended use and technological features of the reprocessed devices do not differ from the legally marketed predicate device(s). Both the reprocessed device(s) and the predicate device(s) have the same materials and product design. The technological characteristics of the reprocessed laparoscopic/endoscopic scissors, dissectors, and graspers are the same as those of the legally marketed predicate devices. Alliance Medical Corporation's reprocessing of laparoscopic/endoscopic instruments includes removal of adherent visible soil and decontamination. Only lumened laparoscopic/endoscopic instruments are reprocessed, allowing for thorough rinsing of all cleaning agents from the instruments, as well as complete removal of residual moisture. Laparoscopic/endoscopic **scissors** are tested for cutting function. **Graspers** and **dissectors** are tested for the ability of the jaws to grasp appropriately. Instruments with **ratchet jaws** are tested for locking and unlocking function. Each individual instrument is tested for appropriate function prior to packaging, labeling, and sterilization operations.
Performance data:	Performance data demonstrates that Reprocessed Laparoscopic/Endoscopic Instruments perform as originally intended.
Conclusion:	In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, Alliance Medical Corporation concludes that the modified device (Reprocessed Laparoscopic/Endoscopic Instruments) is safe, effective and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 8 2001

Mr. Don Selvey
Vice President, Regulatory Affairs
and Quality Assurance
Alliance Medical Corporation
10232 South 51st Street
Phoenix, Arizona 85044

Re: K012638
Trade/Device Name: Alliance Medical Corporation Reprocessed Laparoscopic/Endoscopic Instruments
Regulation Number: 876.1500
Regulation Name: Laparoscope, General & Plastic Surgery
Regulatory Class: II
Product Code: GCJ
Dated: August 10, 2001
Received: August 13, 2001

Dear Mr. Selvey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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K012638

Indications for Use Statement

510(k) Number (if known): K012638

Device Name: Alliance Medical Corporation Reprocessed Laparoscopic/Endoscopic Instruments

Indications for Use: Reprocessed laparoscopic/endoscopic instruments, including scissors, dissectors, and graspers, are to be used for patients requiring minimally invasive surgical procedures to manipulate and manage internal soft tissue by grasping, cutting or dissecting tissue.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Walker

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

Prescription Use ✓ (per 21 CFR 801.109) or Over-the-Counter Use ____

510(k) Number # K012638